++ CAHPS® trademark status.
++ NQF endorsement status.
++ Survey administration instructions.
++ Data analysis instructions.
++ Guidelines for reporting survey data.

If you wish to provide comment on this information collection, please submit your comments as specified in the **ADDRESSES** section of this request for information.

Comments must be received on/by January 19, 2016.

III. Collection of Information Requirements

This RFI does not impose any information collection requirements. We believe it is a solicitation of comments from the general public. As stated in the implementing regulations of the Paperwork Reduction Act of 1995 (PRA) at 5 CFR 1320.3(h)(4), it is exempt from the requirements of the PRA (44 U.S.C. 3501 *et seq.*) .

The data collected via this RFI will be used to develop the LTCH PEC Survey. While surveys are generally subject to the requirements of the PRA, we believe the LTCH PEC Survey is exempt. Section I of this RFI explains that we plan to collect this information in support of the NQS and, under sections 1886(m)(5) and 1890A(e) of the the Act and develop the LTCH PEC Survey into a quality measure that we may consider proposing for adoption in the LTCH Quality Reporting Program (QRP). In accordance with section 102 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–110), the PRA shall not apply to the collection of information for the development of quality measures.

Also, as stated earlier in section I. of this RFI, we will develop the CMS LTCH PEC Survey in accordance with CAHPS® Survey Design Principles and are developing this survey and plans to submit the resulting instrument to AHRQ for recognition as a CAHPS® survey. Upon receiving recognition as a CAHPS® survey and prior to implementation, CMS will submit the CAHPS recognized LTCH PEC Survey through the OMB approval process. At that time, the public will have the opportunity to review, comment, or review and comment on the proposed information collection request prior to its submission to OMB for review and approval.

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

Dated: November 6, 2015.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2015–29622 Filed 11–19–15; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3328–NC]

Medicare Program; Request for Information To Aid in the Design and Development of a Survey Regarding Patient and Family Member Experiences With Care Received in Inpatient Rehabilitation Facilities

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Request for information.

SUMMARY: This request for information will aid in the design and development of a survey regarding patient and family member experiences with the care received in inpatient rehabilitation facilities (IRFs).

Comment Date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on January 19, 2016.

ADDRESSES: In commenting, refer to file code CMS–3328–NC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3328–NC, P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3328–NC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments only to the following addresses:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

FOR FURTHER INFORMATION CONTACT: Judith Harvilchuck, Ph.D., 410–786–3527.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday

through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

I. Background

In accordance with section 399HH of the Public Health Service Act (PHSA), as added by section 3011 of the Patient Protection and Affordable Care Act (Pub. L. 111–148, enacted on Mar. 23, 2010), the Department of Health and Human Services (HHS) developed the National Quality Strategy (NQS), which is led by the Agency for Healthcare Research and Quality (AHRQ), to create national aims and priorities to guide local, state, and national efforts to improve the quality of health care (*http://www.ahrq.gov/workingforquality/*). The NQS established three aims supported by six priorities.

The three aims are as follows:

- *Better Care:* Improve the overall quality, by making health care more patient-centered, reliable, accessible, and safe.
- *Healthy People/Healthy Communities:* Improve the health of the U.S. population by supporting proven interventions to address behavioral, social, and environmental determinants of health in addition to delivering higher-quality care.
- *Affordable Care:* Reduce the cost of quality health care for individuals, families, employers, and government.

The six priorities are: (1) Making care safer by reducing harm caused by the delivery of care; (2) ensuring that each person and family are engaged as partners in their care; (3) promoting effective communication and coordination of care; (4) promoting the most effective prevention and treatment practices for the leading causes of mortality, starting with cardiovascular disease; (5) working with communities to promote wide use of best practices to enable healthy living; and (6) making quality care more affordable for individuals, families, employers, and governments by developing new health care delivery models.

To support the collection of data that can be used to pursue these aims and progress on these priorities in the IRF setting, we are developing a survey hereinafter referred to as the ''IRF Patient and Family Member Experience of Care (PEC) Survey,'' which supports the NQS goal of Better Care and the priorities of:

- Ensuring that each person and family are engaged as partners in their care (priority #2); and
- Promoting effective communication and coordination of care (priority #3).

Under authority of sections 1886(j)(7) and 1890A(e) of the Social Security Act (the Act), we plan to collect this information in support of the NQS aims. When this survey is fully developed, we will consider proposing it for adoption as a quality measure under the IRF Quality Reporting Program (QRP) (for details on CMS' measure development process, please see the Blueprint at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/MeasuresManagementSystemBlueprint.html*). We intend to develop the IRF PEC Survey in accordance with Consumer Assessment of Healthcare Providers and Systems (CAHPS®) Survey Design Principles and submit the resulting instrument to AHRQ for recognition as a CAHPS® survey. CAHPS® Survey Design Principles and implementation instructions can be found at *https://www.cahps.ahrq.gov/about-cahps/principles/index.html.*

We have previously implemented a number of nationwide patient experience CAHPS® surveys in both inpatient and outpatient settings and for different services. Specifically, we implemented CAHPS® surveys for Medicare health and drug plans, inpatient hospitals, home health agencies, in-center dialysis facilities, hospices, and Accountable Care Organizations, and recently developed a CAHPS® survey for outpatient and ambulatory surgery centers; and we have begun development of a Long Term Care Hospital Patient Experience of Care Survey. The planned IRF PEC Survey differs from other CMS PEC surveys because the target population for the IRF PEC Survey consists of patients who have significant rehabilitation needs, some of which are complex. Although the vast majority of IRFs exist as part of acute care hospitals, IRF patients are specifically excluded from the survey population of the Hospital CAHPS® surveys for purposes of CMS' Hospital Inpatient Quality Reporting Program.

IRFs are hospitals or units of acute care (or critical access) hospitals that provide intensive rehabilitation services to patients typically following an injury, illness, or surgery.[1] Patient who are admitted require intensive rehabilitation therapy services, as documented by physician assessment, which are uniquely provided in IRFs. Although the intensity of these services can be reflected in various ways, the generally-accepted standard by which it is typically demonstrated in IRFs is by the provision of intensive therapies at least 3 hours a day for 5 days a week.[2] This resource-intensive inpatient hospital environment is for patients who, due to the complexity of their nursing, medical management, and rehabilitation needs, require an inpatient stay and an interdisciplinary team approach to the delivery of rehabilitation care.

We believe that the following aspects of IRF care that would have to be taken into consideration in developing the survey, but we invite comment on these considerations as well as any potential omissions from this list:

- Complexity of rehabilitation needs and long-term options.
- Interdisciplinary team approach to care delivery.
- Coordination and collaboration on patient and medical goals of care when many patients have goals of returning to their home- or community-based setting.
- Patient and family education on the types and limitations of rehabilitative services and long-term levels of care and supports following IRF discharge.
- Addressing psycho-social needs related to the oftentimes unexpected setback that resulted in the IRF stay.

Given the unique environment and patient population of the IRF setting, we are exploring the level of adequacy of existing patient experience of care instruments designed for other settings for capturing IRF care experiences. Therefore, we are in the process of reviewing potential topic areas (as discussed in section II. of this RFI), as well as publicly available instruments and measures, for the purpose of developing an IRF PEC Survey that will enable objective comparisons of IRF experiences across the country. A rigorous, well-designed IRF PEC Survey will allow us to understand patient experiences throughout their IRF care, as reported by the patients themselves, if possible, or by family members. Should we ultimately adopt the IRF PEC Survey as a quality measure in the IRF QRP, the public reporting of data from the measure could help consumers make more informed decisions about different IRF providers, as well as drive improvements in the quality of IRF care.

II. Solicitation of Information

We are soliciting the submission of suggested topic areas such as communication with providers, rehabilitation, functional status, pain management/control or non-pain symptom management (including

[1] *http://www.medpac.gov/documents/reports/mar14_ch10.pdf?sfvrsn=0.*

[2] *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/Inpatient_Rehab_Fact_Sheet_ICN905643.pdf.*

offering of alternative non-opioid pain management, discussion of safe storage and proper disposal of opioids, screening for overdose risk, and review the history of substance use), discharge planning, family training, rehabilitation services, medical and nursing care, interdisciplinary team goal setting and care planning. We are also soliciting information on publicly available instruments for capturing patients' and family members' experiences with IRF care in a variety of formats (for example, standardized, computer readable format) that can be collected by providers or CAHPS® survey vendors. We are interested in suggested topic areas and publicly available instruments that can measure the quality of care from the patients' and/or family members' perspective in IRFs within acute-care hospitals, critical access hospitals, and free-standing facilities; instruments that can be used to track changes over time; and items that are developed for and/or can be modified to address low case volume. Existing instruments are preferred if they have been tested, have been found to have a high degree of reliability and validity, and for which there is evidence of wide use in one or more patient care settings, including those in rural and frontier communities. Instruments capable of risk adjustment, and/or instruments that minimize duplication of efforts and/or that utilize common quality measures, where available, are preferred. Whenever possible, preference will be given to quality measures identified by the Secretary under section 1139A or 1139B of the Act, or endorsed under section 1890 of the Act.

The following information would be especially helpful in any comments responding to this request for information:

- A brief cover letter summarizing the information requested for submitted instruments and topic areas, respectively, and how the submitted materials could be used to help fulfil the intent of the survey.
- (Optional) Information about the person submitting the materials for the purpose of follow-up questions about the submission, which includes the following:
  - ++ Name.
  - ++ Title.
  - ++ Organization.
  - ++ Mailing address.
  - ++ Telephone number.
  - ++ Email address.
- When submitting topic areas, we encourage including, to the extent available, the following information:
  - ++ Detailed descriptions of the suggested topic area(s) and specific purpose(s).
  - ++ Relevant peer-reviewed journal articles or full citations.
- When submitting publicly available instruments or survey questions, we encourage including to the extent available the following information:
  - ++ Name of the instrument.
  - ++ Indication that the instrument is publicly available.
  - ++ Copies of the full instrument in all available languages.
  - ++ Topic areas included in the instrument.
  - ++ Measures that can be derived from data collected using the instrument.
  - ++ Instrument reliability (internal consistency, test-retest, etc.) and validity (content, construct, criterion related).
  - ++ Results of cognitive testing (one-on-one testing with a small number of respondents to ensure that they understand the questionnaire.)
  - ++ Results of field testing.
  - ++ Current use of the instrument (who is using it, what it is being used for, what population it is being used with, how instrument findings are reported, and by whom the findings are used).
  - ++ Relevant peer-reviewed journal articles or full citations.
  - ++ CAHPS® trademark status.
  - ++ NQF endorsement status.
  - ++ Survey administration instructions.
  - ++ Data analysis instructions.
  - ++ Guidelines for reporting survey data.

If you wish to provide comments on this information collection, please submit your comments as specified in the **ADDRESSES** section of this request for information.

Comments must be received on/by January 19, 2016.

III. Collection of Information Requirements

This RFI does not impose any information collection requirements. We believe it is a solicitation of comments from the general public. As stated in the implementing regulations of the Paperwork Reduction Act of 1995 (PRA) at 5 CFR 1320.3(h)(4), it is exempt from the requirements of the PRA (44 U.S.C. 3501 *et seq.*).

The data collected via this RFI will be used to develop the IRF PEC Survey. While surveys are generally subject to the requirements of the PRA, we believe the IRF PEC Survey is exempt. Section I. of this RFI explains that we plan to collect this information in support of the NQS and, under sections 1886(j)(7) and 1890A(e) of the Act and develop the IRF PEC Survey into a quality measure that we may consider proposing for adoption in the IRF Quality Reporting Program (QRP). In accordance with section 102 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–110), the PRA shall not apply to the collection of information for the development of quality measures.

Also, as stated earlier in section I. of this RFI, we will develop the CMS IRF PEC Survey in accordance with CAHPS® Survey Design Principles and are developing this survey and plans to submit the resulting instrument to AHRQ for recognition as a CAHPS® survey. Upon receiving recognition as a CAHPS® survey and prior to implementation, CMS will submit the CAHPS recognized IRF PEC Survey through the OMB approval process. At that time, the public will have the opportunity to review, comment, or review and comment on the proposed information collection request prior to its submission to OMB for review and approval.

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

Dated: November 6, 2015.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2015–29623 Filed 11–19–15; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0145]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Improving Food Safety and Defense Capacity of the State and Local Level: Review of State and Local Capacities

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.